

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

VIVEVE, INC.

Plaintiff;

vs.

THERMIGEN, LLC;
THERMIAESTHETICS, LLC; AND
RED ALINSOD, M.D.

Defendants.

NO. 2:16-cv-1189

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Viveve, Inc. (“Viveve” or “Plaintiff”), by and through counsel, files this Complaint against Defendants ThermiGen, LLC (“ThermiGen”), ThermiAesthetics, LLC (“ThermiAesthetics”), and Dr. Red Alinsod (“Defendants,” collectively) for patent infringement and alleges, based on information and belief, personal knowledge and publicly available information, with respect to the infringing activity as follows:

THE PARTIES

1. Viveve is a corporation incorporated under the laws of the State of Delaware with its principal place of business at 150 Commercial Street, Sunnyvale, California 94086.
2. ThermiGen is a corporation incorporated under the laws of the State of Texas with its principal place of business at 8304 Esters Boulevard, Suite 890, Irving, Texas 75063.
3. ThermiAesthetics is a corporation incorporated under the laws of the State of Texas with its principal place of business at 8304 Esters Boulevard, Suite 890, Irving, Texas 75063.

4. Red Alinsod, M.D., is a urogynecologist who assessed TheremiGen's "ThermiRF" technology for use with vaginal laxity, and has "signed on" with ThermiGen to bring the treatment, called "ThermiVa," to patients and physicians. ThermiGen selected Dr. Alinsod to head the ThermiVa Center for Physical Education for temperature controlled radiofrequency and he is Chairman of the Women's Health Clinical Advisory Board at ThermiAesthetics. *See, e.g.*, <http://www.prweb.com/releases/2015/09/prweb12942495.htm>; <https://urogyn.org/thermiva>.

JURISDICTION AND VENUE

5. Plaintiff repeats and re-alleges the allegations contained in Paragraphs 1–4 as though fully set forth in their entirety.

6. This action arises under the patent laws of the United States, Title 35, United States Code § 1, *et seq.* This Court has original subject matter jurisdiction over this case for patent infringement under 28 U.S.C. §§ 1331 and 1338(a).

7. Personal jurisdiction exists generally over the Defendants because each has sufficient minimum contacts with the forum as a result of business conducted within the State of Texas and within the Eastern District of Texas. Personal jurisdiction also exists specifically over the Defendants because each, directly or through subsidiaries or intermediaries, makes, uses, offers for sale, sells, imports, advertises, makes available, instructs others to use, and/or markets products and services within the State of Texas, and more particularly, within the Eastern District of Texas, that infringe the patent-in-suit, as described more particularly below.

8. This Court has personal jurisdiction over Defendants ThermiGen and ThermiAesthetics.

9. ThermiGen and ThermiAesthetics are incorporated in Texas.

10. ThermiGen and/or ThermiAesthetics have made, used, offered to sell, and/or sold a ThermiVa device in Texas and/or this District.

11. ThermiGen and/or ThermiAesthetics have provided to at least one medical provider in Texas and/or this District instructions on how to perform the ThermiVa procedure.

12. At least one medical provider has performed the ThermiVa procedure in this District.

13. Accordingly, ThermiGen and/or ThermiAesthetics have induced medical providers in this District to commit infringing acts and contributed to medical providers' commission of infringing acts in this District.

14. This Court has personal jurisdiction over Defendant Dr. Alinsod.

15. Dr. Alinsod is an executive of ThermiAesthetics.

16. Dr. Alinsod has had a contractual relationship with ThermiAesthetics.

17. Dr. Alinsod has an ongoing contractual relationship with ThermiAesthetics.

18. Dr. Alinsod has instructed at least one physician in Texas on how to perform the ThermiVa procedure.

19. Dr. Alinsod has instructed at least one physician in this District on how to perform the ThermiVa procedure.

20. Dr. Alinsod is Chairman of the Women's Health Clinical Advisory Board at ThermiAesthetics.

21. The ThermiAesthetics Women's Health Clinical Advisory Board has hosted Clinical Advisory Council (CAC) meetings in Texas and/or this District.

22. The ThermiAesthetics Women's Health Clinical Advisory Board has scheduled CAC meetings for the near future in Texas and/or this District.

23. CAC meetings pertain, at least in part, to the ThermiVa procedure.
24. At CAC meetings, attendees can ask Dr. Alinsod questions.
25. The website urogyn.org includes information regarding the Alinsod Institute and the ThermiVa procedure.
26. The website urogyn.org is accessible to medical providers and/or residents of this District.
27. Accordingly, Dr. Alinsod has committed infringing acts in this District and induced medical providers in this District to commit infringing acts.
28. Venue is proper in this District under 28 U.S.C. §§ 1391(b)–(c) and 1400(b), because the Defendants have individually transacted business in this District and/or have committed acts of patent infringement in this District.

PATENT-IN-SUIT

29. U.S. Patent No. 8,961,511 (“the ’511 Patent”), entitled “Vaginal Remodeling Device and Methods,” is valid and enforceable, and was duly issued in full compliance with Title 35 of the United States Code by the USPTO on February 24, 2015.

30. The ’511 Patent claims priority from U.S. Provisional Application No. 60/743,247, filed February 7, 2006. A true and correct copy of the ’511 Patent is attached hereto as Exhibit A.

31. Viveve is the owner by assignment of the ’511 Patent with sole rights to enforce the ’511 Patent and sue infringers.

32. The ’511 Patent recites claims directed to remodeling female genital tissue by, for example, applying heat to the target tissue. In certain cases, the application of heat tightens the tissue, which may be a consequence of thermal denaturation of collagen as well as a longer term

healing response in the tissue that includes an increased deposition of collagen. Ex. A at Abstract.

33. In some instances, the methods are performed using a treatment tip including an energy delivery element adapted to heat the target tissue. *Id.* at 2:25-40.

DEFENDANTS' USE OF INFRINGING PRODUCTS AND PROCESSES

34. Defendant ThermiGen markets a vaginal reconstruction procedure under the name ThermiVa that incorporates Viveve's patented methods. *See, e.g.,* <https://www.thermi.com/treatments/thermiva>. Like the '511 Patent, the ThermiVa procedure utilizes a radio frequency, thermistor tip to control heat delivery to specific genital tissues to tighten the target zone. *See, e.g.,* Ex. B ("Temperature Controlled Radiofrequency for Vulvovaginal Laxity"); Ex. C ("ThermiVa RF Generator System User Manual").

35. ThermiGen's marketing efforts include providing instructional materials that instruct third-party medical providers on how to practice the patented methods. ThermiGen makes these instructional materials available throughout the country, including to interested medical providers and patients in this District. *See, e.g.,*

<https://www.thermi.com/treatments/thermiva>; Ex. C.

36. Defendant ThermiAesthetics makes, offers for sale, and sells a product, referred to as the ThermiVa Temperature Controlled Radio Frequency ("TTCRF") device, ThermiVa RF Generator System, and/or the ThermiVa device (hereinafter the "ThermiVa device") that is specifically designed, marketed, and sold for use in methods that practice the patented techniques. Ex. B; Ex. C.

37. Defendants ThermiGen and ThermiAesthetics provide marketing materials, including instructional materials that instruct third-party medical providers on how to practice

the patented methods using the ThermiVa device. *See, e.g.*, Ex. C; <https://www.thermi.com/treatments/thermiva>; https://www.youtube.com/watch?v=LE-S_qUNtdY. ThermiGen and ThermiAesthetics make these instructional materials available throughout the country, including to interested medical providers and patients in this District.

38. Defendant Dr. Alinsod has used, offered for sale, and/or sold the vaginal reconstruction procedure under the name ThermiVa that incorporates Viveve's patented methods. *See, e.g.*, Ex. B; https://www.youtube.com/watch?v=ywlHI4bL8_4; <https://urogyn.org/thermiva>.

39. Dr. Alinsod has made instructional materials that instruct third-party medical providers on how to practice the patented methods. *See, e.g.*, Ex. B; https://www.youtube.com/watch?v=LE-S_qUNtdY; https://www.youtube.com/watch?v=ywlHI4bL8_4. These instructional materials are available throughout the country, including to interested medical providers and patients in this District.

40. Defendant ThermiGen's activities as described above in Paragraphs 34 - 37 have been conducted with full knowledge of the '511 Patent. Indeed, ThermiGen filed U.S. Patent Application 14/591,002 (the "'002 Application") on January 7, 2015, which lists Dr. Alinsod as an inventor. On January 18, 2016, ThermiGen filed an information disclosure statement (IDS) (attached as Exhibit D) to the U.S. Patent and Trademark Office identifying the '511 Patent as potential prior art to its '002 Application. ThermiGen and Dr. Alinsod therefore have knowledge of the '511 Patent. With knowledge of the '511 Patent, ThermiGen has continued to provide instructional materials that willfully encourage third parties to use the ThermiVa remodeling procedure, knowing that such use was infringing the '511 Patent.

41. Defendant ThermiAesthetics's activities as described above in Paragraphs 36 - 37 have been conducted with full knowledge of the '511 Patent. With knowledge of the '511 Patent, ThermiAesthetics has continued to make, sell, and offer for sale the ThermiVa device and has continued to provide instructional materials that willfully encourage third parties to use the ThermiVa device in the ThermiVa remodeling procedure, knowing that such use was infringing the '511 Patent.

42. Defendant Dr. Alinsod's activities as described above in Paragraphs 38 - 39 have been conducted with full knowledge of the '511 Patent. With knowledge of the '511 Patent, Dr. Alinsod has continued to use the ThermiVa remodeling procedure and has continued to provide instructional materials that willfully encourage third parties to use the ThermiVa remodeling procedure, knowing that such use was infringing the '511 Patent.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 8,961,511

43. Viveve re-alleges and incorporates by reference the allegations contained in paragraphs 1 through 42 of this Complaint.

44. In the United States, Defendant Dr. Alinsod has directly infringed and continues to directly infringe literally or under the Doctrine of Equivalents, one or more claims of the '511 Patent, including, but not limited to, Claim 51, by using, providing, selling, and/or offering for sale services that utilize the patented methods. Dr. Alinsod is liable for patent infringement in violation of 35 U.S.C. § 271(a).

45. By way of example, Claim 51 of the '511 Patent recites:

A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a mucosal surface of the labia minora.

46. Dr. Alinsod's service remodels female genital tissue comprising at least one of vulva, introitus, and vagina tissue. For example, Dr. Alinsod describes "using the TTCRF device (ThermiVa, ThermiAesthetics, Inc., Southlake, TX) [to treat several patients] for approximately 5 minutes per zone (left and right labia majora; and the ventral, dorsal, left and right surfaces of the vaginal wall)." Ex. B at 19.

47. Dr. Alinsod's service using the ThermiVa device heats the target tissue. For example, Dr. Alinsod's service heats tissue to a "target temperature range of 40°C to 45°C for approximately 3–5 minutes per zone (or longer, depending on heat tolerance)." *Id.*

48. Dr. Alinsod's service remodels the therapeutic zone of target tissue by heating a mucosal surface of the labia minora. For example, patients are treated "externally on the labia/clitoral complex." *Id.* at 21.

49. Defendants ThermiGen, ThermiAesthetics and Dr. Alinsod are liable for actively inducing infringement of one or more claims of the '511 Patent, including, but not limited to, Claim 51, by knowingly taking active steps to encourage and facilitate direct infringement by others, such as third-party medical providers, who use the patented methods. ThermiGen, ThermiAesthetics, and Dr. Alinsod are liable for patent infringement in violation of 35 U.S.C. § 271(b).

50. By way of example, Defendants knowingly provide literature, instructional videos, and other instructional materials encouraging and facilitating direct infringement of the patented methods by at least third-party medical providers. *See, e.g.*, Ex. B; https://www.youtube.com/watch?v=LE-S_qUNtdY; <https://www.thermi.com/treatments/thermiva>. And Defendants, upon information and belief, have knowledge of the '511 Patent. Ex. D.

51. On information and belief, Defendant ThermiAesthetics is a contributory infringer of one or more claims of the '511 Patent, including, but not limited to, Claim 51, by making, selling, offering to sale, and/or importing within or to the United States components, for example, the ThermiVa device, that is a material part of the patented invention, knowing the same to be specially made or specially adapted for use in the infringement of at least one claim of the '511 Patent. On information and belief, the ThermiVa device is not a staple article or commodity suitable for substantial, non-infringing use. ThermiAesthetics is liable for patent infringement in violation of 35 U.S.C. § 271(c).

52. The Defendants' infringement of the '511 Patent has caused substantial and irreparable harm to Viveve, and will continue to cause such harm unless and until their infringing activities are enjoined by this Court. For this harm, Viveve does not have an adequate remedy at law.

53. Pursuant to 35 U.S.C. § 284, Viveve is entitled to damages adequate to compensate it for the infringement, in an amount to be determined at trial, but in no event less than a reasonable royalty.

54. On information and belief, the Defendants' infringement of the '511 Patent has been willful and deliberate, making this an exceptional case entitling Viveve to recover additional damages and attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Viveve prays for relief as follows:

- A. Judgment that the Defendants have infringed, induced others to infringe, and/or contributorily infringed the '511 Patent;
- B. An order preliminarily and permanently enjoining the Defendants from further infringing the '511 Patent;
- C. An award of damages pursuant to 35 U.S.C. § 284 for past and future damages and including prejudgment interest;
- D. A declaration that the Defendants' infringement was willful and deliberate, and an increase to the award of damages of three times the amount found or assessed by the Court, in accordance with 35 U.S.C. § 284;
- E. An order for an accounting of damages from Defendants' infringement;
- F. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and
- G. Any additional award or further relief the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Viveve hereby demands a trial by jury on all claims and issues so triable.

Dated: October 21, 2016

Respectfully submitted,

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